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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/606,982

06/26/2003

Michael P. Lewis

6440

9809

7590

09/06/2005

KEELING HUDSON LLC

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EXAMINER

DEMILLE, DANTON D

ART UNIT

PAPER NUMBER

3764

DATE MAILED: 09/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/606,982		LEWIS, MICHAEL P.	
	Examiner		Art Unit	
	Danton DeMille		3764	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 12-22, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 23-27, 30 and 31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>10-21-03</u> | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's response to the restriction requirement has been considered. An action on the merits of claims 1-11, 23-27, 30, 31 follows. Claims 12-22, 28, 29 are withdrawn.

Drawings

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 29-31. There is a bracket that encompasses figures 5A-D. These figures are separate and independent. They are not exploded part of a single drawing. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. Claims 5, 6, 9, 10, 24-27, 30, 31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, there is no clear antecedent basis for “said flexible surface layer”.

In claim 6, there is no clear antecedent basis for “said flexible surface layer, flexible bladder section, and flexible liner layer”.

In claim 9, there is no clear antecedent basis for “said flexible liner layer”.

In claim 10, there is no clear antecedent basis for “the flexible bladder section”.

In claims 24-27, 30 and 31, there is no clear antecedent basis for “said pulsation”.

Moreover, it is not clear how this limitation further limits the structure recited in the claims. This limitation recites intended use of the device. There is no positive further structural limitation recited.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. **Claims 1-4, 24-27, 30, 31 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Van Brunt ‘785.**

6. Broadly, Van Brunt teaches a cuff that has an electromechanical actuator 14 integral to the cuff. The actuator being attached to a top side of the cuff at first end 12a. The actuator is rigidly attached to an actuator extension 26 that is attached to a tension attachment 46 to the second end 12b of the cuff. To any extent applicant’s actuator is distant from the tension attachment during use so is Van Brunt’s actuator. There is the actuator extension between the

actuator and the tension attachment same as applicant's invention. While Van Brunt may not teach the intended use of counterpulsation it nevertheless teaches all of the positive structural limitations claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 6-9, 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Brunt '785.**

9. While Van Brunt appears silent with regard to the exact dimensions of the device such details are well within the realm of the artisan of ordinary skill. Van Brunt's device would appear to fall within the claimed ranges. If not inherent, it would have been obvious to one of ordinary skill in the art to modify Van Brunt to vary the size of the device to accommodate different sized individuals or to accommodate different areas of the body.

10. **Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Brunt '785 as noted above and further in view of Arkans.**

11. Arkans teaches cavities 70a-c between sections of the bladder to allow the skin of the patient to breathe. It would have been obvious to one of ordinary skill in the art to further modify Van Brunt to include spaced cavities as taught by Arkans to allow the skin of the patient to breathe.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-11, 23-27, 30, 31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-37 of U.S. Patent No. 6,620,116. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to leave out the details of the means for electronically receiving physiological data.

Information Disclosure Statement

14. The information disclosure statement filed 6/26/03 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited Chinese patent document and the Cohen non-patent literature or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.


15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Danton DeMille whose telephone number is (571) 272-4974.

The examiner can normally be reached on M-Th from 8:30 to 6:00. The examiner can also be reached on alternate Fridays.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Greg Huson, can be reached on (571) 272-4887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

1 September 2005


Danton DeMille
Primary Examiner
Art Unit 3764